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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,965	12/02/1997	GEORGE H. LOWELL	359292000110	9909

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VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/982,965	LOWELL, GEORGE H.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2004 has been entered.

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Winkler, Group Art Unit 1648.**

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3-4, and 7-13 under 35 U.S.C. 103(a) as being unpatentable over Lowell et al. (U = Science (1988) Vol. 240, pp. 800-802), Lowell et al. (V = Journal of Experimental Medicine (1988) Vol. 167, pp. 658-663), Smith et al. (W = Technological Advances in Vaccine Development (1988) pp. 651-659) and Avraham et al. (X = VII International Conference on AIDS, Florence (June 16-21, 1991) Abstract No. TH.A.67) in view of Ratner et al. (Y = Nature (1985) Vol. 313, pp. 277-284) **is maintained** for the reasons of record set forth in the prior Office Actions.

The amendments are drawn to the addition of process steps to the product claims. M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and

defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

The claimed invention is directed to compositions capable of eliciting antibodies. Applicant's claims are not directed to a vaccine or to a protective immune response to HIV. In Applicant's sole independent claim, claim 1, Applicant has claimed an immunogenic composition comprising proteosomes, gp160 protein, and a pharmaceutical carrier. As such, the only requirement of the claimed invention is that the composition elicits the production of antibodies to gpl60.

Each of the primary references teaches the use of similar immunogenic proteosome-protein compositions. Both Lowell et al. (U) and Smith et al. (W) teach the use of proteosomes to enhance the immunogenicity of circumsporozoite peptides. Lowell et al. (V) teach the use of proteosomes to enhance the immunogenicity of membrane glycoprotein peptides. Avraham et al. (X) teach the use of proteosomes to enhance the immunogenicity of HIV-AIDS membrane glycoprotein peptides. Avraham et al. also teach the use of a carrier. The primary references do not teach an immunogenic proteosome-gpl60 composition. However, Ratner et al. (Y) teach the gene sequence for a glycosylated exterior membrane protein (page 282. column 1). This glycosylated exterior membrane protein is gp160. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the various immunogenic peptides disclosed in the primary references for the gp160 peptide of Ratner et al.

because gp160 was known to be an envelope protein, and it is well known in the viral art that envelope proteins are highly immunogenic compounds. Avraham et al. provide motivation by teaching the use of immunogenic proteosome compositions in the context of HIV-AIDS. Furthermore, Ratner et al. provide motivation by teaching that the complete nucleotide sequence of the HTLV-III provirus will provide useful information for the development of diagnostic and therapeutic reagents to AIDS (page 280,column 1).

Applicants' argue unexpected results regarding the titer improvement for the disclosed gp160 complex (see response March 8, 2004, page 7). This argument is not convincing because it would have been obvious to the ordinary artisan that increasing the concentration of peptide in a vaccine formulation would increase immunogenicity of the composition. The instant claims are directed at a proteosome:gp160 composition the claims contemplate increasing the gp160 in relation to the proteosome concetration. Lowell et al. (U) teaches that increasing the peptide concentration in a peptide : proteosome mixture increases the immunogenicity of the peptide (see table 2, page 801). Therefore, Applicnats' arguments of unexpected results is not convincing based on the skill of the ordinary artisan and the information disclosed in the prior art that increasing peptide in the mixture increases the immunogenicity against the peptide.

Applicant argues that Smith et al. and Aversham et al. are silent as to the details of the technique employed in Applicant's invention. However, Applicant's sole independent claim (claim 1), does not claim a technique. Rather, claim 1 is directed towards a composition. Applicant points to the unpredictable nature of antibody titers between peptides of different size. Applicant also point to variation in the degree of immunogenicity achieved by the different techniques. However, Applicant is reminded that there is a certain level of unpredictability and

variation in any scientific experimentation-but that the degree of unpredictability and variation, in order to be considered nonobvious, must exceed the expectations of the person of ordinary skill in the art. In the present instance that degree has not been exceeded because, despite any unpredictability and variation, a person of ordinary skill in the art at the time of invention would not have been dissuaded or discouraged from substituting gp160 peptide of Ratrier et al. for the other peptides taught by the cited primary references to induce antibody production.

As stated in the prior Office Actions, dependent claims 10 and 11 only add further limitations that the complexes are formed by lyophlization or dialysis, both very well known techniques in the art for protein isolation, purification, or storage.

Dependent claim 12 only adds the further limitation that the complexes are formed by mixing. However, the limitation of "mixing" is a very well known technique in the art for combining two or more components and does not render the claim nonobvious.

Dependent claims 3, 4, and 13 only add the further limitation of an adjuvant. However, a person of ordinary skill in the art would have found it obvious to add any adjuvant to increase immunogenicity because, by definition, adjuvants increase immunogenicity.

Conclusion

No claims allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 2/7/05